Re-evaluation Note REV2011-04

Amitraz

(publié aussi en français)

22 November 2011

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0630 (print)
1925-0649 (online)

Catalogue number: H113-5/2011-4E (print version)
H113-5/2011-4E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2011

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

1.0 Background

Amitraz is one of the active ingredients under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The purpose of this Re-evaluation Note is to notify registrants, pesticide regulatory officials, and the Canadian public of interim label amendments for the domestic class end-use product containing amitraz registered to control ticks on dogs.

Amitraz is an acaricide/insecticide, which acts by interacting with octopamine receptors in the tick nervous system. The domestic class end-use product registered to control ticks on dogs is a 62.5 cm ready-to-use plastic collar containing 2.48 g of amitraz. The product is not to be used on puppies (dogs under 12 weeks of age) or on cats.

2.0 Regulatory Strategy

The PMRA re-evaluation of amitraz is ongoing. Based on the PMRA Regulatory Directive DIR2002-01, *Canadian Label Improvement Program for Pesticides Used on Companion Animals*, and the Companion Animal Safety study submitted by the registrant, the PMRA is requiring the registrant of the domestic class end-use product to make changes to the product label to enhance safety of companion animals. The PMRA identified data gaps in the toxicology database for amitraz. The implementation of these label improvements is considered a first step in the re-evaluation process for amitraz. Appendix I lists all label amendments. The registrant of the technical grade active ingredient will be notified of additional data requirements by letter.

In 2006, the USEPA announced that the American registrant of amitraz made a business decision, not triggered by risk concerns, to market two sizes of dog collars: a 45 cm dog collar containing 1.8 g of amitraz (for dogs below 27 kg) and a 62.5 cm dog collar containing 2.4 g of amitraz (for dogs above 27 kg). The Canadian registrant is encouraged to submit a similar proposal to the PMRA.

3.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2002-01 can be found on the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service.
Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

Appendix I Label Amendments for Products Containing Amitraz

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, and precautionary statements. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The label of the domestic end-use product (Registration No. 24496) must be amended as follows:

I) The following statements must be included in the section entitled DIRECTIONS FOR USE:

DO NOT APPLY MORE THAN ONE COLLAR PER DOG.

Replace this collar no more than once every 90 days. A veterinarian should be consulted when pest infestation continues to be a problem on the pet.

II) The following statements must be included in a section entitled PRECAUTIONS.

PETS: There is a risk of collar breakage and ingestion if a collar is worn by unattended dogs that play by mouthing each other in the neck area. If collar is missing from a dog, search for, retrieve and recover the entire collar. Sensitivities may occur after using any pesticide for pets. Smaller animals may be more likely to experience an adverse reaction. Observe carefully.

III) The following statement under the section entitled DIRECTIONS FOR USE must be removed from the product label:

Do NOT use this product on dogs or cats at the same time or within 30 days before or after treatment with, or exposure to, pesticides or chemicals.